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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,470	02/26/2004	Satoshi Takasaka	PC 26222A	9092

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PHARMACIA CORPORATION  
GLOBAL PATENT DEPARTMENT  
POST OFFICE BOX 1027  
ST. LOUIS, MO 63006

EXAMINER
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CLAYTOR, DEIRDRE RENEE

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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07/19/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/787,470	<b>Applicant(s)</b> TAKASAKA, SATOSHI	
	<b>Examiner</b> Renee Claytor	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

### ***Response to Arguments***

Applicant's arguments over the 35 U.S.C. § 103 rejection over Jain et al. in view of Cardenas et al. has been considered and the arguments are not found to be persuasive. Applicant's argue that drugs such as Loxonin and Voltaren are major pain killers but do not work to treat pain associated with spinal cord injury. This argument is

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not persuasive because as evidenced by Goodman & Gilman's: The Pharmacological Basis of Therapeutics (page 1673), which teaches that the glucocorticoid methylprednisolone is the main treatment option for the treatment of spinal cord injury. Methylprednisolone is also used in pain management in other conditions as well, including as palliative therapy for cancer patients (see Zoorab et al., Am Fam Phy, 1998, page 8) showing that a pain killer that is effective for treating pain associated with cancer is also effective in treating spinal cord injury. Therefore, because one or two major painkillers are not effective in treating spinal cord injury does not mean that all painkillers will be ineffective in treating spinal cord injury.

Applicants further argue that there is difficulty in categorizing pain caused by spinal cord injury as taught by Cardenas et al. and state that pain associated with spinal cord injury as a different pain from conventional pains. This argument is not persuasive because Cardenas et al. discusses the state of the art in categorizing pain associated with spinal cord injury and describes classification systems that include musculoskeletal pain and visceral pain in addition to neuropathic type pains (see complete introduction). As further evidence of this, Putzke et al. (Spinal Cord, 2002, 40, 118-127) teach different forms of pain associated with spinal cord injury which include such feelings of aching, cramping and dull as being forms of musculoskeletal pain (see Tables 2, and 5-7). Therefore, Cardenas et al. as well as Putzke et al. teach various forms of pain involved with spinal cord injury, which includes neuropathic pain, as well as musculoskeletal or mechanical pain, which exemplifies that spinal cord injury is not associated with one type of pain. Applicant's further argue that Jain et al. does not

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disclose treatment of sildenafil in association with neuropathic pain and that one of skill in the art, recognizing that pain killers such as Loxonin and Voltaren, which are effective at reducing nociceptive pain but ineffective at reducing pain associated with spinal cord injury, would not be motivated to try sildenafil in treating spinal cord injury. This argument is not found persuasive because as discussed above, Cardenas et al. and Putzke et al. teach that there are different forms of pain associated with spinal cord injury, which includes musculoskeletal pain as well. The language of present claim 1 is drawn to "a method for alleviating pain....." and does not specify what kind of pain; therefore, the combined teachings of Jain et al. and Cardenas et al. meet the limitations of the claim by teaching treatment of pain by administration of sildenafil.

Applicant's arguments over the 35 U.S.C. § 103 rejection over Jain et al. in view of Cardenas et al. and further in view of Maw et al. (U.S. Patent 6,586,439) have been considered and are not persuasive. Applicants argue that Maw does not teach the treatment of pain or spasticity in a patient suffering from spinal cord injury by the administration of sildenafil. The inclusion of the Maw et al. reference fills in the deficiencies of Jain et al. and Cardenas et al. because Maw et al. teach oral administration of sildenafil and therapeutic dose ranges.

The rejection is given below for Applicant's convenience.

***Claim Rejections – 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al.

(Brain Research 909, 2001, 170-78) in view of Cardenas et al. (Arch Phys Med Rehabil, Vol. 83, Dec. 2002).

Jain et al. teach that sildenafil is a cGMP PDE5 inhibitor that is useful in the treatment of pain (see in particular results and figures).

Jain et al. does not specifically teach that sildenafil or cGMP PDE5 inhibitors treat pain associated with spinal cord injury.

Cardenas et al. teach that chronic pain is associated with spinal cord injury (see whole document).

It is therefore obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of Jain et al., which teach that sildenafil is a cGMP PDE5 inhibitor and is useful in the treatment of pain, with Cardenas et al. which teach that pain is associated with spinal cord injury. One having ordinary skill in the art at the time the invention was made would be motivated to combine the teachings of Jain et al., with Cardenas et al. because the prior art teaches that sildenafil treats pain and spinal cord injury is associated with pain.

Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al. (Brain Research 909, 2001, 170-78) in view of Cardenas et al. (Arch Phys Med

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Rehabil, Vol. 83, Dec. 2002) as applied to claim 1 above, and in further view of Maw et al. (U.S. Patent 6,856,439).

Jain et al. and Cardenas et al. teach that sildenafil treats pain and that pain is associated with spinal cord injury.

Jain et al. and Cardenas et al. do not teach the route of administration or the dosage of sildenafil.

Maw et al. teach a pharmaceutically active compound comprised of a cGMP PDE5 inhibitor that is used to treat various disorders, including female sexual pain disorder and sexual dysfunction due to spinal cord injury (Col. 25, lines 13-20). They further teach that the compound will be administered orally (encompassing claim 2, Col. 25, lines 52-53) and a dose range of tablets as being between 0.01 mg and 500 mg (encompassing claim 3; Col. 27, lines 30-31).

It is therefore obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of Jain et al., which teach that sildenafil is a cGMP PDE5 inhibitor and Cardenas et al. which teach that spinal cord injury is associated with pain, with the teachings of Maw et al. which teach a composition comprised of a cGMP PDE5 inhibitor to treat various disorders, including female sexual pain disorder and sexual dysfunction in patients suffering from spinal cord injury. One having ordinary skill in the art at the time the invention was made would be motivated to combine the teachings of Jain et al. and Cardenas et al. with Maw et al. to obtain an efficacious compound to alleviate pain associated with spinal cord injury.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

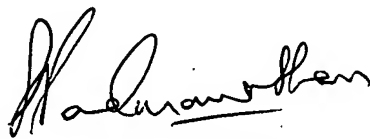
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER